510(k) Summary
807.92(c)

JUL 11 2012

SPONSOR **807.92(a)(1)**

Company Name: Arlington Contact Lens Services, Inc.

Company Address: 4265 Diplomacy Dr.
Columbus, Ohio 43228

Telephone: 614-921-2522

Contact Person: Peter Clarkson

Summary Preparation Date: March 13. 2012

DEVICE NAME **807.92(a)(2)**

Trade Name: Contact Lens Case (Multiple Brand Names)
Common/Usual Name: Contact Lens Case
Classification Name: Soft (hydrophilic) contact lens care products
Regulation Number: 886.5928
Product Code: LRX
Device Class: Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Device Name*	*K Number*
Ningbo Kaida Rubber and Plastic Technology Co., Ltd.	Contact Lens Case	K071081

DEVICE DESCRIPTION **807.92(a)(4)**

The AC Branded Contact Lens Cases consists of a lens case base with dual adjoining wells for the containment of fluid. The case cover are two screw top caps. All the variant models have a capacity of over 3.0 ml in each case well, thus, any contact lens can be fully immersed into the chambers.

DEVICE INTENDED USE **807.92(a)(5)**

The applicant contact case is to be used by the contact lens wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses while not in use. Intended for chemical disinfection only. Not designed for heat disinfecting system.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Comparison Elements	AC Lens Applicant Device	Predicate Device

Device Name	Multiple Brand Names	Multiple Brand Names (K071081)
Classification Name	Contact Lens Case	Contact Lens Case
Product Code	LRX	LRX
Comparison Statement	**The applicant device has same classification information as the predicate device.**	
Intended Use	The applicant contact case is to be used by the contact lens wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses while not in use. Intended for chemical disinfection only. Not designed for heat disinfecting system.	The Applicant contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing contact lenses while not being worn. The applicant device is not designed for heat disinfecting system. Use only with chemical disinfection.
Indications	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard Contact Lenses.	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard Contact Lenses.
Disinfection Type	Chemical Disinfection, Not Heat Disinfection	Chemical Disinfection, Not Heat Disinfection
Design	Two adjoining wells with screw top into which respective lenses are immersed	Two adjoining wells with screw top into which respective lenses are immersed
Main Material	Polypropylene (PP) and Acrylonitrile-Butadiene-Styrene copolymer (ABS)	SK Corporation Polypropylene (PP) R370Y with certificated quality Acrylonitrile-butadiene-styrene copolymer (ABS) PA – 757K.
Comparison Statement	**The applicant device has a similar design and uses the same materials as the predicate device. The only difference is the colorant**	
Screw on Caps	Yes	Yes
R/L indications on well bottom and/or cap top	Yes	Yes
Non-vented caps	Yes	Yes

CONCLUSION **807.92(b)(3)**

The applicant contact lens case is similar to the predicate device in

- intended use,
- materials and
- design.

The applicant contact lens case introduces no new questions concerning safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arlington Contact Lens Services, Inc.
c/o Christian Smith
Consultant, Smith Associates, Inc.
1468 Harwell Ave
Crofton, MD 21114

JUL 11 2012

Re: K120969
Trade/Device Name: AC Lens Branded Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: June 13, 2012
Received: June 14, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120969

Indications for Use

510(k) Number (if known): K120969

Device Name: Contact Lens Case

Indications for Use:

The applicant contact case is to be used by the contact lens wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses while not in use. Intended for chemical disinfection only. Not designed for heat disinfecting system.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___✓___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120969